DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2005

Proton Health Care Ltd.
c/o Mr. Kevin Walls, RAC
Principal Consultant
Regulatory Insight Inc.
13 Red Fox Lane
Littleton, CO 80127

Re: K051565
Trade Name: Proton Digital Blood Pressure Monitor Models PH168A, PH168E, PH168W, and PH888HA, and Proton Blood Pressure Monitor Model PHC888JA
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 31, 2005
Received: September 1, 2005

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051565

Device Names:

1. Proton Digital Blood Pressure Monitor, Model PH168A
2. Proton Digital Blood Pressure Monitor, Model PH168E
3. Proton Digital Blood Pressure Monitor, Model PH168W
4. Proton Blood Pressure Monitor, Model PHC888JA
5. Proton Digital Blood Pressure Monitor, Model PH888HA

Indications for Use:

All five models automatically measures human's Systolic, Diastolic blood pressure and heart rate using the oscillometric method. All values can be read out in one LCD Panel.

The intended use of Models PH168A, PH168E and PH168W is for age 16 and above.

The intended use for the Models PHC888JA and PH888HA is for adult patients whose arm circumference is between 24-32cm (approx. 8.7" to 12.6").

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051565